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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,207	03/04/2005	Annette Freund	BASF.10020	4630
45473	7590	02/03/2006	EXAMINER	
HUTCHISON & MASON PLLC PO BOX 31686 RALEIGH, NC 27612			GITOMER, RALPH J	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/526,207	Applicant(s) FREUND ET AL.	
	Examiner Ralph Gitomer	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) 22,26,27 and 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,21,23-25,28-34,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1655

Applicant's election with traverse of Group I, claims 20, 21, 23-25, 28-34, 38, 39, in the reply filed on 12/14/05 is acknowledged. The traversal is on the ground(s) that the special technical feature is GTP cyclohydrolase II and all the groups contain that feature. This is not found persuasive in part because the groups are distinct because they do not all contain that feature. For example claim 22 is directed to a sequence that does not contain the enzyme. And some of the claimed methods are distinct methods such as claims 26 and 27 where only one single method is proper to be elected.

The requirement is still deemed proper and is therefore made FINAL.

The certified priority document has been received and priority is granted to 9/6/02. Please update the continuing information regarding priority in the preamble of the specification. An abstract on a separate page is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Herz.

Art Unit: 1655

Herz (WO 00/40744 A1) "Method for Screening for Inhibitors of Riboflavin Biosynthesis" teaches on page 4 first full paragraph, GTP cyclohydrolase II is susceptible for specific inhibition and thus is a promising target for screening for inhibitors for fungi. On page 7 first full paragraph, the enzyme sequence may be a fungal type for finding fungicides. On page 14 second paragraph, a method is taught for determining GTP cyclohydrolase II by action of a fungal reductase which can be expressed in modified E. coli. The reaction requires NADH as a cosubstrate and the result is monitored photometrically at 340 nm to determine NADH consumption.

All the features of the claims are taught by Herz for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1655

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21, 31, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herz.

Herz (WO 00/40744 A1) "Method for Screening for Inhibitors of Riboflavin Biosynthesis" teaches on page 4 first full paragraph, GTP cyclohydrolase II is susceptible for specific inhibition and thus is a promising target for screening for inhibitors for fungi. On page 7 first full paragraph, the enzyme sequence may be a fungal type for finding fungicides. On page 14 second paragraph, a method is taught for determining GTP cyclohydrolase II by action of a fungal reductase which can be expressed in modified E. coli. The reaction requires NADH as a cosubstrate and the result is monitored photometrically at 340 nm to determine NADH consumption.

Claim 21 differs from Herz in that it specifies particular sequences.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to select the claimed sequences in view of Herz who teaches sequences because the present claim is so broad that the sequences of Herz would be encompassed by the present claim.

Claim 31 differs from Herz in that the compound is contacted to both the transformed organism and a wild type organism.

Art Unit: 1655

It would have been obvious to one of ordinary skill in this art at the time the invention was made to contact the compound to a transformed organism as taught by Herz and also contact it to a wild type organism as a control because employing a control to obtain a baseline of enzymatic activity is standard in such determinations and various types of standards are taught by Herz.

Claim 33 differs from Herz in that it states the method can be performed as high throughput screening.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to employ high throughput screening in a known assay because one would have a high expectation of success in employing such a well known technique for its known advantages with the expected result. No special features are claimed for such screening.

Claim 34 differs from Herz in that it further verifies the effect of the identified antifungal agent.

It would have been obvious to one of ordinary skill in this art at the time the invention was made to administer any agent identified by the claimed method and such administering would inherently verify such activity. Confirmation steps in identifying pharmaceutical agents is old.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 21, 23-25, 28-34, 38, 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

There are many instances of lack of antecedent basis that require correction. For example, in claim 20(i) "the binding", claim 25 "the enzymatic", claim 29 "the increase", "the absorption" and many others. Claim 20 is directed to identifying agents but lacks any such step. Claim 20 must be carefully rewritten in accordance with standard US patent practice. Standard gerunds for such method claims include determining and correlating. In claim 20, the format is confusing where step (ii) refers to itself. And "selecting by step" is unclear. Claim 23 fails to further limit claim 20. There may be typo regarding the dependency in claim 29. And "the increase" and "the absorption" lack antecedent basis. In claim 31 "capable of" does not positively recite what occurs. In claim 31(c) "the growth", "the viability", and "the transgenic" lack antecedent basis. In claim 34 "via the method is unclear and lacks antecedent basis. In claim 38 "the NADH content" lacks antecedent basis and is unclear.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Revuelta Doval (5,821,090) teaches a sequence similar to Seq. 4 that codes for GTP cyclohydrolase II.

Babyak (6,376,222) teaches sequence 1.

Wang (6,171,598) teaches GTP cyclohydrolase II encoding sequences.

Blau (Biochimica et Biophysica Acta) is directed to finding inhibitors of GTP cyclohydrolase I.

Viitanen (6,146,866, 6,323,013, 6,350,597) are directed to fungal cyclohydrolase II inhibitors and sequences.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1655

RALPH GITOMER
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GROUP 1200